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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,143	01/16/2001	Muraleedharan G. Nair	MSU 4.1-541	4327
21036 7590 04/29/2008 MCLEOD & MOYNE, P.C. 2190 COMMONS PARKWAY OKEMOS, MI 48864				
EXAMINER				
LEITH, PATRICIA A				
ART UNIT		PAPER NUMBER		
1655				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/761,143

**Applicant(s)**

NAIR ET AL.

**Examiner**

Patricia Leith

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-6,15-18,27-30 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,15-18,27-30 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/07/08 has been entered. The amendments filed after final on 12/26/07 will not be entered because Applicant has submitted an amendment on 2/7/08 which draws from the claims of 8/24/07. Thus, it is apparent that Applicant does not want the claims of 12/26/07 entered at this time.

Claims 1, 3-6, 15-18, 27-30 and 34 are pending in the application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

### ***Terminal Disclaimer***

The three (3) terminal disclaimers filed on 8/24/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No.'s 6,818,234, 6,194,469 and 6,676,978 have been reviewed and is accepted. The terminal disclaimers have been recorded.

***Claim Rejections - 35 USC § 112***

Claims 1, 3-6, 15-18, 27-30 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While Applicants have amended claim 1 to read, in-part: "providing a dried mixture of an isolated cyanidin and a lyophilized anthocyanin...", this excerpt still contains the term 'isolated' in conjunction with 'cyanidin'. It has already been established on the record that Applicants have not provided indication that they contemplated a composition comprising an isolated cyanidin with an anthocyanin. That is, Applicants have not disclosed isolating cyanidin and admixing it with a composition containing an anthocyanin, or an anthocyanin alone or, as is now claimed, a lyophilized anthocyanin. While it is accepted, per the Declaration filed by Dr. Nair on 11/16/06, that

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cyanidin is inherent to cherries and thus it is also accepted that cyanidin would be present in the extract produced by Applicants, Applicants proceed to claim what has not been clearly established as their invention according to what was taught in the Instant disclosure.

***Claim Rejections - 35 USC § 103***

Claims 1, 3-6, 15-18, 27-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gryglewski et al. (1987) in view of Lietti et al. (GB 1,589,294). in view of Lenoble et al. (US 5,908,650) in view of Brenner (US 5,462,932 A) in view of Roy (US 4,712,310 A) as keenly discussed in the previous Office action(s).

The teachings of Gryglewski et al., Lietti et al., Brenner and Roy were discussed in previous Office actions. Applicants' arguments toward Hellberg et al. were found persuasive, and hence, this reference has been removed from the rejection.

Again, none of the references specifically suggested the incorporation of a food grade acid.

Lenoble et al. (US 5,908,650) taught that the prior art recognized anthocyanins for their color-imparting influence on foods as well as their

antioxidant capabilities (see citation, *infra*). Lenoble et al. specifically taught the combination of food grade acids such as rosmarinic acid to anthocyanins in order to stabilize (i.e., "prevent the rate of loss of anthocyanin color due to pH, heat and/or light") anthocyanins in food compositions such as solid food and beverages (see entire reference, especially col. 1, lines 18-20, lines 50-59, col. 2, line 57-col. 3, line 5, lines 18-32, please also see col. 1, lines 39-41).

Thus, one of ordinary skill in the art would have been motivated to add an acid such as rosmarinic acid to a composition comprising anthocyanins in order to stabilize the anthocyanins in such a composition. One of ordinary skill in the art would clearly have recognized the advantage of combining such acids with anthocyanin-containing compositions, as Lenoble et al. taught "...we have shown that a water-soluble extract from the common spice of rosemary...is rich in compounds which stabilize and enhance anthocyanin-based color." Thus, the ordinary artisan would have found it predictable to add such an acid to an anthocyanin-containing composition to advantageously "stabilize and enhance" anthocyanins.

Applicants' arguments pertaining to the remainder of the rejection save for Roy et al. are exactly the same arguments as presented at the time of the final Office action. Hence, the rebuttal of said arguments can be found in the final Office action dated November 6, 2007 and are incorporated herein by reference.

Applicants' arguments pertaining to Roy et al. were fully considered, but not found persuasive.

Applicants argue:

Roy teaches compounds which are not chemically related to anthocyanins. The food grade acid used by Applicants is to retard degradation of the anthocyanin in the claimed compositions. The problem Brenner et al<sup>2</sup> deals with is bone loss therapy. One would not use an acid in solution with an anthocyanin as in this reference because of the problem of hydrolysis. This reference is thus remote from the claimed invention

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). While Roy did not teach the compounds of the claimed invention, they clearly teach that lyophilization of known medicinal components was a routine, common procedure in the art of pharmaceutical compounding. It is deemed that lyophilization of products which were already known in the art for having a medicinal effect is *prima facie* obvious absent any clear indication of unexpected results. "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

**...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

[If]... there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

### ***Conclusion***



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith  
Primary Examiner  
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